

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

*Track One Cases*

) MDL 2804

) Case No. 1:17-md-2804

) Judge Dan Aaron Polster

) ORDER DENYING MOTION TO  
) EXCLUDE GRUBER

Before the Court is Defendants' *Daubert* Motion to Exclude the Opinions Offered by Jonathan Gruber (Doc. #: 1916). For the reasons stated below, the motion is **DENIED**.

The Court hereby incorporates the legal standards set forth in the Court's Opinion and Order regarding Defendants' motion to exclude the opinion and testimony of Prof. Meredith Rosenthal, see Doc. #: 2495.

**I. Introduction**

Jonathan Gruber is one of the nation's leading health economists. He received his Ph.D. in Economics from Harvard University and is the Ford Professor of Economics at the Massachusetts Institute of Technology, where he has taught for over 25 years. Gruber directs the Health Care Program at the National Bureau of Economic Research and served as President of the American Society of Health Economists from 2016-2018. He has twice won the International Health Economics Association Kenneth J. Arrow Award for the outstanding health economics paper and has served as the Co-Editor for both the Journal of Public Economics and the Journal of Health Economics. Along with David Cutler, another of Plaintiffs' experts, he won the ASHEcon award for best health economist in the nation age 40 and under in 2006. Gruber has previously

testified in *Int'l Tobacco Partners, Ltd. v. Kline*, 475 F. Supp. 2d 1078, 1082 (D. Kan. 2007) (“Gruber is clearly qualified to testify as an expert in this case.”).

Plaintiffs asked Gruber to compose a report for two purposes. (Doc. #: 1916-5). The first was “to provide, from the perspective of accepted principles of economics, an overview of the nation’s opioid crisis.” Report at ¶ 15 (Doc. #: 1916-5). Second was to address “whether, to a reasonable degree of certainty in the field of economics, the defendants’ shipments of prescription opioids contributed, in whole or in part, to the growth in the misuse of opioids and the increases in licit and illicit opioid-related mortality over the past 20 years, and to explain the bases” for those opinions. *Id.* Gruber reached the following principal conclusions: First, “[t]here is a direct, causal relationship between defendants’ shipments of prescription opioids and the misuse and mortality from prescription opioids, with geographic areas that received higher volumes of per capita shipments of prescription opioids experiencing significantly higher rates of opioid related misuse and mortality, including the Bellwether jurisdictions.” *Id.* at ¶ 16. Second, “[t]here is a direct, causal relationship between defendants’ shipments of prescription opioids and the misuse of and mortality from illicit opioids, including heroin and fentanyl, which accelerated rapidly after 2010.” *Id.* Third, “[t]he significant increases in all-opioid mortality (i.e., mortality from both prescription and illicit opioids) are largely unrelated to trends in non-opioid drug overdoses, changes in population demographics, or local economic conditions.” *Id.* Gruber employed both regression analysis and other mainstream methods of statistical analysis to determine correlation and causation to reach and illustrate his conclusions. He also relied on the work of other economists and epidemiologists, including some who also serve as Plaintiffs’ experts in this case, to support his opinions.

## **II. Discussion**

Defendants do not challenge Gruber's qualifications, but they do ask the Court to exclude his report and testimony, attacking his opinions' relevance or fit with Plaintiffs' case, and offering several arguments relating to the appropriateness and reliability of his methods. Specifically, Defendants assert that Gruber is not using any recognized methodology to sustain his analysis, that whatever methodology he is using is inadequate to support an admissible opinion on causality, that his analysis fails to address the Bellwether counties, and that he impermissibly relies on a supposedly flawed "gateway hypothesis" concerning individuals' transition from prescription opioid addiction to heroin and fentanyl addiction.

### **A. The Reliability of Gruber's Methodology**

#### **1. Graphical Illustrations of Correlation and Gruber's Conclusions on Causation**

Defendants first argue Gruber founds his opinions solely upon unacceptable, unreliable methodologies, finding fault with Gruber's use of what they describe as mere graphical representations of underlying data to support his findings. Motion at 5 (Doc. #: 1916). They claim Gruber was unable "to identify any authoritative source supporting his method at any point during his deposition."

Q. And I'm not focused so much on the graphic itself as the analysis that . . . underlies the graphic; where . . . you take the lowest quartile and the highest

quartile, and you've shown a difference in terms of mortality, growth between those two quartiles. What's the name of that analysis so I can find it in a textbook?

A. I don't know that there's a common name for this analysis that you find in a textbook. . . .

Gruber Dep. Doc. #: 1916-6 at 402:21 - 403:11. Defendants conclude that Gruber's testimony is therefore "not based on any reliable, tested methodology." Motion at 5 (Doc. #: 1916).<sup>1</sup>

To counter this attack, Plaintiffs first point out that Defendants misrepresent Gruber's deposition testimony when they claim he failed to name another source using his method. Plaintiff's Opposition (hereinafter "Opp.") at 6 (Doc. #: 2116). They point to testimony just two pages farther down in the deposition transcript that gainsays Defendants' assertion:

Q. Whether in a textbook or some other source, can you point me to any source that would describe for me the type of, you know, high quartile – highest quartile-lowest quartile analysis that you're doing here and would state that that's an appropriate means to show causation?

\*\*\*

A. Sure. The Evans study that we – Evans, Lieber and Powell study does exactly this kind of analysis . . .

\*\*\*

Q. And the Evans study doesn't purport to show causation, does it?

A. Yes, it does.

Gruber Dep. at 405:5 – 17; 406:15 – 17 (Doc. #: 1916-6).

Plaintiffs thus establish that non-regression methods to demonstrate causation do appear in the peer-reviewed literature, despite Defendants' claims to the contrary.<sup>2</sup> The Court is satisfied

---

<sup>1</sup> Defendants specifically challenge the use of this method in connection with Figures 1.16 - 1.20 and 1.24 - 1.25 and their associated text. Motion at 4 (Doc. #: 1916).

<sup>2</sup> See Opp. at 6 n. 6 (Doc. #: 2116) citing William N. Evans, Ethan M.J. Lieber, Patrick Power, *How the Reformulation of Oxycontin Ignited the Epidemic*; CI(1) Review of Econ. And Statistics 1-15 (Mar. 2019). Plaintiffs also note that Gruber has authored and cites in his Report numerous studies demonstrating relationships in data through the use of graphical analyses. Opp. at 5, n. 5 (Doc. #: 2116). See Michael D. Frakes and Jonathan

that Gruber has not founded his analysis on a non-existent methodology, and notes that Defendants may cross-examine Gruber about his methods. *See United States v. Demjanjuk*, 367 F.3d 623, 634-36 (6<sup>th</sup> Cir. 2004) (trial court did not abuse its discretion in admitting expert testimony that was neither original nor controversial).

## 2. Gruber Bases His Conclusions on Causation Upon a Reliable Methodology

Defendants next assert Gruber has shown only a correlation between Defendants' shipments of opioids and Plaintiffs' harms, and has not demonstrated a causal relationship. Motion at 5-6 (Doc. #: 1916); Reply at 1-3 (Doc. #: 2464). They claim his graphical analyses only show correlation and conclude he sidesteps the work of generating a methodologically appropriate analysis to show causation, asserting that his regression analysis is deficient. Reply at 4 (Doc. #: 2464).

Plaintiffs deny that Gruber used unsound methods to establish causation. They explain that Gruber employed a multiple regression analysis in conjunction with his other accepted forms of statistical analysis to establish the causal relationship between opioid shipments and increased mortality from both prescription and illegal opioids. They also note that Gruber "supplements this analysis by then providing evidence from epidemiological and economic studies that corroborate

---

Gruber, *Defensive Medicine: Evidence from Military Immunity*, Nat'l Bureau of Econ. Research Working Paper 24846 (July 2018); Benjamin D. Sommers and Jonathan Gruber, *Federal Funding Insulated State Budgets from Increased Spending Related to Medicaid Expansion*, Health Affairs 36(5) (May 2017); Jonathan Gruber and Robin McKnight, *Controlling Health Care Costs Through Limited Network Insurance Plans: Evidence from Massachusetts State Employees*, 8(2) Am. Econ. Journal: Econ. Policy 219-250 (2016); Leemore Dafny, Jonathan Gruber and Christopher Ody, *More Insurers Lower Premiums: Evidence from Initial Pricing in the Health Insurance Marketplaces*, 1(1) Am. Journal of Health Econ. 53-81 (2015); Jackson Abaluck and Jonathan Gruber, *Choice Inconsistencies among the Elderly: Evidence from Plan Choice in the Medicare Part D Program*, 101 Am. Econ. Review 1180-1210 (June 2011); *See also* Abby Alpert, David Powell and Rosalie Liccardo Pacula, *Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids*, 10 Am. Econ. Journal: Econ. Policy 1-35 (2018) (Utilizing "Graphical Event Study Results" to support the conclusion that large increases in heroin deaths immediately after reformulation occurred in states with the highest initial rates of OxyContin misuse) (cited in Report ¶ 97 (Doc. #: 1916-5)).

his conclusion that illicit harms since 2010 were a direct result of shipments and licit harms.” Opp. at 17 (Doc. #: 2116).

Gruber’s report is, indeed, replete with graphs intended to visually represent statistical observations generated from data. There is nothing wrong with that. Many of these graphs appear in the Factual Background and Empirical Overview section (Section III) of his report that precedes his causation opinions. Defendants do not appear to challenge this material specifically, and the Court finds it unobjectionable. Because the charts and figures of Section III, which use the modes of analysis that Defendants claim are insufficient to support conclusions concerning causation, do not purport *themselves* to demonstrate causation, but merely illustrate trends and associations, the Court finds Section III admissible in whole. Indeed, the text accompanying each of these Figures explains what relationship the Figure illustrates and even draws attention to the imperfections in the analysis and identifies the measures Gruber took to remedy them. *See, e.g.*, Report at ¶¶ 73-85 (Doc. #: 1916-5). The assiduity with which Gruber points out the imperfections in his own analysis adds to its reliability.

Gruber’s opinions on causation, namely that “the increases in shipments of prescription opioids was [*sic*] a direct and substantial cause of the rapid growth in mortality from both licit and illicit opioid related mortality in the past 20 years,” Report at ¶ 72 (Doc. #: 1916-5), appear to be the primary focus of Defendants’ objections. Motion at 4-6 (Doc. #: 1916). Defendants seek the exclusion of the entirety of Gruber’s report, but specifically call into question Figures 1.16-1.20 and 1.24-1.25, all of which appear in Sections IV and VI. *Id.* at 2, 4.

In Section VI, Gruber does not rely on his graphical analysis (Figures 1.24 and 1.25) to illustrate causation, but merely to show correlations between opioid shipments and crime. Gruber notes that Section VI “briefly reviews evidence of the link between shipments of prescription

opioids and higher levels of crime.” Report at ¶ 108. He explains Figures 1.24 and 1.25 illustrate what the data demonstrate about “whether counties that received more shipments between 1997-2010 experienced lower declines in crime than low shipment counties, as would be expected if opioids contributed to increased criminal behavior.” *Id.* at ¶ 111. In addition, Gruber’s summary of opinions explains that “Section VI establishes that shipments of prescription opioids are also *associated with higher crime.*” *Id.* at ¶ 19.

With respect to Section IV (encompassing Figures 1.16-1.20), which contains Gruber’s challenged opinion on causation, the Court does not agree that Gruber is relying solely on an unacceptable methodology. His own deposition testimony quoted above, selectively omitted by Defendants in the exhibits accompanying their motion, explains the prevalence of this methodology in economic studies and refers to published work that relies on it to demonstrate causation. In addition, as Plaintiffs point out, Gruber uses regression analysis alongside other methods to support his conclusions about causation. Gruber first uses the non-regression methods to establish a correlation between shipments of opioids and increased mortality, the intensity of which suggested causation. *See Etherton v. Owners Ins. Co.*, 829 F.3d 1209, 1220 (10<sup>th</sup> Cir. 2016) (“Although correlation alone may be insufficient to establish causation, it is nonetheless relevant to identifying causal relationships.”) (citations omitted). He then applies multiple regression analysis to control for a range of variables, finding they did not account for the rise in mortality. Report at ¶¶ 74-75 (Doc. #: 1916-5). Taken together, these were the methods Gruber used to reach his conclusion that “the increases in shipments of prescription opioids was a direct and substantial cause of the rapid growth in mortality from both licit and illicit opioid-related mortality in the past 20 years.” Report at ¶ 72 (Doc. #: 1916-5).

The Court concludes that Gruber’s analysis, though imperfect, employs sufficiently reliable methods of economic analysis to withstand *Daubert* scrutiny. *Daubert*, 509 U.S. at 596 (1993) (“Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”). “As long as an expert’s scientific testimony rests upon ‘good grounds, based on what is known,’ it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors’ scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.” *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998) (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993));

### **3. Failure to Address Cuyahoga and Summit Counties**

Defendants also cite Gruber’s omission of data on the bellwether counties in his quartile analysis as a reason to exclude his opinions. They assert his graphs purporting to show “central tendencies” on a national level are misleading in the context of Cuyahoga and Summit Counties. Specifically, Defendants take issue with his top/bottom quartile analysis, pointing out there are “many counties in the top quartile of shipments that exhibit below average mortality rates, while many counties in the bottom quartile of shipments had above average mortality rates.” Motion at 10 (Doc. #: 1916), Reply at 3 (Doc. #: 2464).

In that connection, Defendants further assert “the potential error rate of Gruber’s methodology is high,” partially as a result of what Gruber describes as a “transshipment problem” that arises when individuals transport opioids out of the counties or states into which they were



originally shipped. Motion at 10 (Doc. #: 1916).<sup>3</sup> According to Defendants, Gruber does not sufficiently account for the transshipment problem. They conclude that the transshipment problem, with its attendant “potential error rate” renders shipments an “inaccurate proxy for opioid consumption.” *Id.* at 10-11.

Plaintiffs counter that Gruber’s analysis is not meant to identify local harms in the Bellwether counties, but rather “to establish a consistent relationship between shipments and harms in a large number of different places.” They also point out that Gruber “devotes an entire section of his report to discussing the opioid crisis in these counties, including identifying the amount of prescription opioid shipments Cuyahoga and Summit Counties received relative to the rest of the country, and general fentanyl trends in Ohio.” Opp. at 11, (Doc. #: 2116); Report at ¶¶ 64-71 (Doc. #: 1916-5).

Gruber himself candidly recognizes the analytic challenge transshipments presents, noting in his Report that it “will induce some measurement error into my comparisons, reducing the power of shipments to distinguish high versus low use areas.” Report at ¶ 84 (Doc. #: 1916-5). But he addresses the problem with the tools at hand: “To some extent, I address this measurement error by comparing only the highest and lowest shipment areas in the large county sample discussed above.” *Id.*

None of the supposed flaws Defendants highlight render Gruber’s report and testimony inadmissible under *Daubert*. That Gruber does not respond to every issue Defendants identify, or

---

<sup>3</sup> An example of the “transshipment problem” has been referred to colloquially as the “Blue Highway,” referring to opioids originally shipped to Florida that were then purchased and transferred north to other States. See [https://www.washingtonpost.com/investigations/76-billion-opioid-pills-newly-released-federal-data-unmasks-the-epidemic/2019/07/16/5f29fd62-a73e-11e9-86dd-d7f0e60391e9\\_story.html](https://www.washingtonpost.com/investigations/76-billion-opioid-pills-newly-released-federal-data-unmasks-the-epidemic/2019/07/16/5f29fd62-a73e-11e9-86dd-d7f0e60391e9_story.html) (“The route [of opioids] from Florida to Georgia, Kentucky, West Virginia and Ohio became known as the ‘Blue Highway.’ It was named after the color of one of the most popular pills on the street — 30 mg oxycodone tablets made by Mallinckrodt, which shipped more than 500 million of the pills to Florida between 2008 and 2012.”).

that Plaintiffs will need to address at trial, does not make his opinions inadmissible. The Court recognizes that Plaintiffs' have engaged a number of experts to piece together various elements of their case. Nor does the absence of Bellwether counties in portions of his analysis make it unreliable, though it may be of limited use to Plaintiffs. Neither does the fact that the top/bottom quartile analysis includes individual instances that run counter to the overall trend Gruber seeks to demonstrate pose a serious risk of confusing the jury. And Gruber's recognition of the transshipment problem, and his transparent effort to account for it, actually renders his analysis more reliable, if perhaps less precise and thus less useful to Plaintiffs. Counter-examples or other statistical irregularities, and the potential error rate posed by the transshipment of opioids, go to the weight the trier of fact will give Gruber's report and testimony, not its admissibility. *See Scholz Homes, Inc. v. Wallace*, 590 F.2d 860, 863 (10th Cir.1979) (finding no abuse of discretion in admission of expert testimony where the witness disclosed inadequacies in the information he was relying on, and was subjected to thorough cross examination). *See also United States v. Lang*, 717 Fed. App'x 523, 534 (6<sup>th</sup> Cir. 2010) ("the *Daubert* standard is liberal, and does not require expert opinions to be bulletproof.").

However, the Court finds that Defendants' have aptly pointed out that Gruber has not demonstrated that Defendants' shipments of prescription opioids caused harms specifically in Cuyahoga and Summit Counties. Reply at 3 (Doc. #: 2464). Gruber implicitly admits as much. Consequently, Gruber may not testify at trial to that effect.

#### **4. Relies on Flawed Gateway Analysis.**

Defendants also seek to exclude Gruber's opinion concerning the so-called "gateway hypothesis" presented by Gruber, and also by Anna Lembke and Katherine Keyes, two of Plaintiffs' other experts, on the ground that their opinions are unreliable and should be excluded. Reply at 4-5 (Doc. #: 2464). Broadly speaking, the gateway effect involves patients who develop

addictions to prescription opioids and then go on to become addicted to illicit opioids. In this connection, Defendants assert Gruber relies on methodologically flawed epidemiological literature and “completely ignores evidence contradicting the gateway hypothesis.” Motion at 11 (Doc. # 1916). In particular, they fault Gruber for failing to accord greater significance to the modest proportion of prescription opioid users who eventually abuse heroin. *Id.* Defendants emphasize that Gruber himself acknowledged “that the percentage of prescription opioid users who go on to abuse heroin is in the range of 1%.” Motion at 11 (Doc. #: 1916).

Plaintiffs respond that Gruber appropriately bases part of his analysis on reliable epidemiological and economic literature to conclude that “the illicit opioid crisis that started in 2010 is the direct consequence of the defendants’ shipments of prescription opioids in prior years.” Opp. at 12 (Doc. #: 2116); Report at ¶ 99 (Doc. #: 1916-5). They also argue that the existence of competing or contradictory studies on a particular topic is not a proper basis for excluding an expert’s opinion on that topic. Opp. at 11-14 (Doc. #: 2116).

Plaintiffs are correct that Gruber, an economist, is permitted to found his opinions not only on economics literature, but also on the work of scholars and other experts in other fields – here, epidemiology. *See DeLuca v. Merrell Dow Pharms., Inc.*, 911 F.2d 941, 954 (3d Cir. 1990) (“The reliability of expert testimony founded on reasoning from epidemiological data is generally a fit subject for judicial notice; epidemiology is a well-established branch of science and medicine, and epidemiological evidence has been accepted in numerous cases.”). In addition, Plaintiffs do not contest the notion that only a small proportion of prescription opioid users become addicted to illegal opioids. Rather, their logic runs in the other direction: they focus on the substantial percentage of heroin and fentanyl users who used prescription opioids before moving on to illicit

ones. Report at ¶¶ 89-93 (Doc. #: 1916-5). Thus, the one percent statistic is of no great relevance to Plaintiffs' case.

For reasons more fully explained in the Court's Order Denying Defendants' Motion to Exclude Experts re: "Gateway Hypothesis," Doc. #: 2518, the supposed defects Defendants point out in the literature Keyes and Lembke rely on in their reports are not so substantial that they offend *Daubert* standards of reliability. *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, 2010 WL 1796334, at \*3 (N.D. Ohio May 4, 2010) ("*Daubert* neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance.") (internal quotation marks omitted). As the Sixth Circuit has explained, "flaws in methodology uncovered by peer review do not necessarily equate to a lack of scientific validity, since the methods may be based on scientific principles and the alleged flaws go merely to the weight, not the admissibility of the evidence and the testimony." *United States v. Bonds*, 12 F.3d 540 at 559 (6<sup>th</sup> Cir. 1993).

### **B. Fit and Relevance**

Defendants assert "Gruber does not offer causation opinions that advance Plaintiffs' theories." Motion at 12 (Doc. #: 2116); Reply at 5-6 (Doc. #: 2464). This supposed lack of fit stems from the absence of the Bellwether counties from Gruber's top/bottom quartile analysis, his failure to isolate the harms supposedly caused by individual defendants, and the inclusion of shipments from non-defendants in his analysis. Motion at 12-14 (Doc. #: 1916).

Plaintiffs respond that Gruber's national data is relevant because it helps establish the broader national context of the opioid crisis, including general trends, and will illuminate other evidence they will present about "the causal connection specifically in Summit and Cuyahoga Counties. Opp. at 10, n. 7 (Doc. #: 2116). Plaintiffs next point out they have engaged other experts

to “analyze the impact of individual Defendants’ misconduct.” Opp. at 15 (Doc. #: 2116). Plaintiffs assert the “absence of specific Defendant-level analysis does not undermine the relevance of Prof. Gruber’s opinion that greater prescription opioid shipments led to increased harms.” *Id.*

The Court does not agree that Gruber’s opinions are irrelevant. *Daubert*’s fit requirement is a liberal one that seeks to ensure evidence is relevant to the issues to be tried, or will be helpful to the trier of fact. *See United States v. Bonds*, 12 F.3d 540 at 555 (6<sup>th</sup> Cir. 1993) (expert testimony must “assist the trier of fact to understand the evidence or to determine a fact in issue.”). Evidence is relevant if it “(a) has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action.” FED. R. EVID. 401.

The purpose of Gruber’s analysis is to “demonstrate a connection between shipments and harms in a large number of different places.” Motion at 10 (Doc. #: 2116). In his analysis, he included areas outside of the Bellwether counties, and included shipments by manufacturers or distributors that may not be in this MDL or may not be defendants in the upcoming trial. But the data he analyzed and the opinions he offers are not irrelevant under Rule 401 and *Daubert*. At the appropriate time, Plaintiffs will have to show actual harms to Cuyahoga and Summit Counties caused by the very defendants that are before the court. Gruber’s opinions and testimony, like those of numerous other experts, are not meant to be conclusive in themselves. Gruber’s opinions are relevant bricks in the evidentiary edifice Plaintiffs intend to construct.

Defendants next argue that Gruber “attribute[s] all opioid-related harms to the Defendants,” including harms caused by illicit opioids, without any underlying support; and that he identifies forces beyond Defendants’ control that contributed to illicit opioid use by individuals

with opioid use disorder, without analyzing the degree to which those external factors caused illicit opioid use. Motion at 13 (Doc. #: 1916).

The Court does not construe these supposed flaws as invoking the issue of fit; indeed, they relate to opinions and analysis that are patently relevant. They are methodological criticisms Defendants may address by confronting the witness during cross examination. “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking but admissible evidence.” *Daubert*, 509 U.S. at 596.

### **III. Conclusion**

For the foregoing reasons, Defendants’ *Daubert* Motion to Exclude the Opinions Offered By Jonathan Gruber is **DENIED**.

**IT IS SO ORDERED.**

/s/ Dan Aaron Polster August 26, 2019  
**DAN AARON POLSTER**  
**UNITED STATES DISTRICT JUDGE**